CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE

BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

HOSPITAL PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT INSTRUCTIONS

Purpose of the Self-Inspection Report

The Pharmacist-in-Charge (PIC) and all pharmacists on duty are responsible for ensuring that their pharmacies comply with all state and federal laws governing pharmacy practice. The primary purpose of this form is to guide you through a self-inspection that will help you identify and correct areas of non-compliance with state and federal law. Board inspectors will also use the completed form to evaluate the pharmacy's level of compliance.

When a Board inspector identifies an area of deficiency, he or she may issue a Deficiency Notice. The PIC is required to respond in writing. Identifying and correcting an area of non-compliance *before* the Board inspection can eliminate the Deficiency Notice. *Note that neither the self-inspection nor Board inspection evaluates your compliance with all the laws and rules of the practice of pharmacy.*

When conducting your self-inspection, it is important to take the time to review the relevant sections of law and regulations and then to personally verify that your pharmacy is in compliance. Avoid *assuming* that your pharmacy is compliant even if "that's the way it has been for years." Note that not having (or not being able to readily retrieve) required documents and records is a common deficiency cited during unannounced inspections. Maintain all such documents in a well-organized manner, such as a binder, and accurately describe the location(s) of the required documents on your *Self-Inspection Report*, if the required documents are readily available to the inspectors, even when you are not present during the inspection, you can reduce your chance of receiving a Deficiency Notice in this area.

If you have questions during your self-inspection, you may contact an inspector by emailing customerservice.dpr@state.de.us or call (302) 744-4500.

When to Complete Self-Inspection Report

The PIC of a Delaware-licensed hospital pharmacy must complete this *Pharmacist-in-Charge Self-Inspection Report*:

- within 30 days of your first being designated as PIC, ***and***
- by February 1 of each year while you continue as the PIC.

Section 3.1.2.7 of the Board's Rules and Regulations describes this requirement. Failure to complete the *Self-Inspection Report* when required, as explained above, may result in disciplinary action.

Completing and Retaining the Report

☐ Complete all items on the self-inspection report form.

- The form provided online is fillable and savable on your computer. It is suggested that you print the form and complete it by hand as you inspect the various aspects of your pharmacy. You may then transcribe your responses to the fillable form.
- Carefully confirm whether or not you are compliant and mark the appropriate box to the right of each item. If you have any deficiencies please correct them and explain what measures you took and the date of correction next to the question.

☐ Review the report with your staff pharmacists, technicians and interns.

☐ ***INFORM ALL PHARMACISTS AND PHARMACY STAFF WHERE THE SELF INSPECTION FORM IS LOCATED. THE STAFF MUST BE ABLE TO LOCATE THIS FORM AT THE TIME OF ANY BOARD OF PHARMACY INSPECTION***

☐ ***Print out and Sign*** the completed report form.

☐ Retain the completed and signed printout of the form on-site at the pharmacy so that it is immediately available for inspection at all times, even if you are not present when an unannounced inspection occurs.

- Retaining a copy of the completed form on your computer is ***not*** sufficient.
- ***Do not mail the completed form to the Pharmacy Board office.***

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HOSPITAL PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT

Date PIC Self-Inspection was performed: _____ /_____ /_____

PHARMACY INFORMATION

1. Name of Pharmacy (as shown on license): _____
2. Delaware Pharmacy License Number: A3 - _____ Controlled Substances Registration PH - _____
3. DEA Registration #: _____
4. ***Location Address***: _____
   Street (*No PO Boxes*)
5. _____ _____ _____
   City State Zip
6. Phone: _____ Fax: _____ Email: _____
7. Is the pharmacy open 24 hours a day? **Yes** ☐ **No** ☐
   - **If NO, enter hours of operation:**

PHARMACY DEPARTMENT HOURS				
Weekdays	_____	AM to	_____	PM
Saturday	_____	AM to	_____	PM
Sunday	_____	AM to	_____	PM
Others	_____	AM to	_____	PM

8. Are any satellite pharmacies located in the institution? **Yes** ☐ **No** ☐
   - **If YES, answer the following:**
     a. Enter hours of operation:

PHARMACY DEPARTMENT HOURS				
Weekdays	_____	AM to	_____	PM
Saturday	_____	AM to	_____	PM
Sunday	_____	AM to	_____	PM
Others	_____	AM to	_____	PM

     b. List the locations of all satellite pharmacies : _____
     _____

Is access to the pharmacy limited to authorized personnel and does documentation of access exist? **Yes** ☐ **No** ☐

9. **PHARMACY PERSONNEL INFORMATION**
10. PIC Name (as shown on license) _____ Pharmacist License No A1 - _____
11. Enter date (month/day/year) that you became PIC for this pharmacy: _____

Attach a separate sheet listing the name and Delaware license number of all other registered pharmacists who will be working in the hospital. Exclude *only* outpatient pharmacists.

Attach another separate sheet listing the name and certificate number (if available) of all support personnel including pharmacy technicians, pharmacy interns, and pharmacy students.

12. Answer the following questions about supportive personnel.

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Have you verified if all of your practitioners have proper prescribing credentials (NPI, and DEA)?	**Yes** ☐ **No** ☐	
Are all supportive personnel under immediate supervision of a pharmacist (24 *Del. C.*§2507)?	**Yes** ☐ **No** ☐	
Do the pharmacy technicians meet the requirements of Section 19 of the Pharmacy Rules and Regulations?	**Yes** ☐ **No** ☐	

13. **PHARMACY PERSONNEL INFORMATION, Continued**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is pharmacist "on-call" service available?	**Yes** ☐ **No** ☐	
Is pharmacy using remote order entry?	**Yes** ☐ **No** ☐	
• **If YES**, are the pharmacists who are processing the orders licensed in the State of Delaware?	**Yes** ☐ **No** ☐	

14. **RECORDS AND OTHER DOCUMENTS**

List where each of the following items is located inside the pharmacy. ***Be as specific as possible.***

RECORD	LOCATION
PIC Self-Inspection Reports for last three years	
Current written biennial controlled substance inventory	
Perpetual inventory of Schedule II medications	
Schedule II-V invoices for last three years	
Completed CII order forms (DEA form 222) for last three years	
Latest version of USP 797 and USP 795	
Support personnel training manual and documentation of training	

15. **REFERENCE MATERIALS**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are reference materials current and available in either hard copy or electronic form?	**Yes** ☐ **No** ☐	
Do the reference materials include all of the following as required by the sections of the Pharmacy Rules and Regulations shown?		
• Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed to patient (Section 3.3.2.1)?	**Yes** ☐ **No** ☐	
• Provide information helpful in the counseling of patients on the use of drugs dispensed (Section 3.3.2.2)?	**Yes** ☐ **No** ☐	
• Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice (Section 3.3.2.3)?	**Yes** ☐ **No** ☐	
• Include a list of therapeutic equivalents for drugs dispensed (Section 3.3.2.4)?	**Yes** ☐ **No** ☐	
• Include current Delaware and federal laws and regulations governing pharmacy and controlled substances (Section 3.3.2.5)?	**Yes** ☐ **No** ☐	
• Provide any other information necessary to ensure the safe and effective practice of pharmacy for the specific practice setting (Section 3.3.2.6)?	**Yes** ☐ **No** ☐	
Do the reference materials include alerts and other correspondence from the Board of Pharmacy or Office of Controlled Substances?	**Yes** ☐ **No** ☐	

16. **PHARMACY POLICIES & PROCEDURES**

In addition to location, list policy number and page where each of the following is found.

POLICY/PROCEDURE	LOCATION	POLICY NUMBER & PAGE
Requisition and dispensing of pharmaceuticals		
Monitoring & removing recalled drugs from all areas in the hospital		
Withdrawal of outdated and deteriorated drugs from all areas in the hospital		
Automated dispensing systems		
Delegation for authority when PIC is not available		
Compounding sterile and non-sterile medications		
Repackaging		
Medication errors/adverse drug reactions		
Drug storage throughout the hospital		
Security procedures addressing access to medications		
Stop order policy and standing order policies		
Night cabinet/emergency supply use		
Distribution of drugs through the hospital		
Nursing administration procedures		
Quality assurance program		
Discharge medication policy		
Medications brought in by patients		
Investigational drug use		
Self-administration		

17. **LICENSES & PERMITS**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Have you verified that all wholesalers from which you purchase medication are licensed/registered in Delaware? Enter names and license/ registration numbers of primary and secondary wholesalers: Primary: _____ _____ Secondary: _____ _____	**Yes** ☐ **No** ☐	
Have you verified that all your outsourcing facilities are compliant with USP 797?	**Yes** ☐ **No** ☐	
• Are all outsourcing pharmacies registered with the FDA?	**Yes** ☐ **No** ☐	
• Enter names of the outsourcing pharmacies of compounding products: _____ _____		
Are all pharmacists, technicians and interns aware that they should report arrests, convictions, and suspected and known violations to the Board?	**Yes** ☐ **No** ☐	
Are the pharmacy's federal and state registrations/permits current and posted?	**Yes** ☐ **No** ☐	
Are all pharmacist licenses, intern pharmacist licenses and certified technician registrations current and posted in the pharmacy?	**Yes** ☐ **No** ☐	

18. **PHYSICAL FACILITIES Section 10.2.1.1 of the Pharmacy Rules and Regulations**

INSPECTION QUESTIONS		CORRECTIVE ACTION/DATE
Does the pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices including a sink with hot and cold water, shelves, refrigerator/freezer, narcotic cabinets and safes, and counter areas which are adequate to avoid crowding?	**Yes** ☐ **No** ☐	
Is the temperature monitored and maintained (keep logs for refrigerator and freezer)?		
• Room temperature maintained at (58°-77°F)?	**Yes** ☐ **No** ☐	
• Refrigerator temperature maintained (36°- 46°F)?	**Yes** ☐ **No** ☐	
• Freezer temperature maintained at (-13°-14°F)?	**Yes** ☐ **No** ☐	
Are medications stored within the manufacturer or USP recommended temperatures?	**Yes** ☐ **No** ☐	
Are medications stored separately from food and employee medications?	**Yes** ☐ **No** ☐	
Is the pharmacy area, kept clean and free of clutter (including refrigerator, sink, counting trays, automated dispensing machines, and floors, etc.)?	**Yes** ☐ **No** ☐	
Does the pharmacy have all the required equipment and is the equipment in good working order?	**Yes** ☐ **No** ☐	

19. **SECURITY 24 *Del. C.* §2533**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is there adequate security control for the pharmacy department?	**Yes** ☐ **No** ☐	
• Does anyone other than pharmacy personnel have access to the pharmacy area?	**Yes** ☐ **No** ☐	
• Does the procedure for storage and documentation of the use of a spare key prevent authorized access?	**Yes** ☐ **No** ☐	
• Is there a procedure for storage and documentation of an extra set of keys in order to prevent unauthorized access?	**Yes** ☐ **No** ☐	
• Describe the security procedures: _____ _____ _____ _____ _____		
Are controlled substances in a locked and secured area?	**Yes** ☐ **No** ☐	

20. **NURSING STATIONS**

. INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is a monthly inspection of each nursing station performed?	**Yes** ☐ **No** ☐	
• Is documentation of monthly inspections of each nursing station available?	**Yes** ☐ **No** ☐	
Does each nursing station have sufficient size, space, sanitation, lighting, ventilation and environmental control for adequate dispensing, and storage of drugs and devices?		
• **If NO**, explain: _____ _____	**Yes** ☐ **No** ☐	
Are outdated or discontinued products routinely checked?	**Yes** ☐ **No** ☐	
• Is there documentation of this activity and procedure?	**Yes** ☐ **No** ☐	
Are temperatures monitored and maintained as follows?		
• Room temperature maintained at (58°-77°F)?	**Yes** ☐ **No** ☐	
• Refrigerator temperature maintained (36°- 46°F)?	**Yes** ☐ **No** ☐	
• Freezer temperature maintained at (-13°-14°F)?	**Yes** ☐ **No** ☐	
• Medications stored within the manufacturer or USP recommended temperatures?	**Yes** ☐ **No** ☐	

NURSING STATIONS, Continued

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are daily logs for refrigerator and freezer temperatures kept and tracked?	**Yes** ☐ **No** ☐	
• If temperatures are out of range, is corrective action taken and documented?	**Yes** ☐ **No** ☐	
Are drugs properly secured?	**Yes** ☐ **No** ☐	
Are medications stored separately from food?	**Yes** ☐ **No** ☐	
Are disinfectants and drugs for external use are stored separately?	**Yes** ☐ **No** ☐	
Does the distribution, administration and disposition of controlled substances audits indicate proper recordkeeping and administration?	**Yes** ☐ **No** ☐	
Are emergency drug supplies and floor stock levels properly maintained?	**Yes** ☐ **No** ☐	

21. **COMPOUNDING PHARMACY Section 5.1.6 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is all compounding (including reconstituting antibiotics) performed only by the R.Ph.?	**Yes** ☐ **No** ☐	
• **If NO**, is a log maintained showing the identity of the compounding person?	**Yes** ☐ **No** ☐	
If compounding is done by support personnel, does the R.Ph. check each step?	**Yes** ☐ **No** ☐	
Is the pharmacy performing sterile compounding? • **If NO**, skip to the **BULK MANUFACTURING/RE-PACKING** section.	**Yes** ☐ **No** ☐	
What type of sterile compounding is being prepared?	**Low Risk** ☐ **Medium Risk** ☐ **High Risk** ☐	
Is a policy and procedure manual in place for sterile compounding?	**Yes** ☐ **No** ☐	
Are annual competencies completed for all staff involved in sterile compounding?	**Yes** ☐ **No** ☐	
Are all required logs maintained per ***USP Chapter 797*** regarding cleaning and maintenance of all sterile compounding areas and ante area?	**Yes** ☐ **No** ☐	
Is documentation of IV hood certification and testing available?	**Yes** ☐ **No** ☐	

22. **BULK MANUFACTURING/RE-PACKING Section 6.3 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is the pharmacy performing re-packing? • **If NO,** skip to **PATIENT PROFILES** section.	**Yes** ☐ **No** ☐	
Does the re-packing log show the following?		
• Date packaged?	**Yes** ☐ **No** ☐	
• Control?	**Yes** ☐ **No** ☐	
• Expiration date?	**Yes** ☐ **No** ☐	
• Manufacturer?	**Yes** ☐ **No** ☐	
• Name and strength of drug?	**Yes** ☐ **No** ☐	
• Person who prepared the re-packing?	**Yes** ☐ **No** ☐	
• Person checking the re-packing?	**Yes** ☐ **No** ☐	

23. **PATIENT PROFILES Section 5.1.10 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
What type of profile do you use? ☐ **Manual** ☐ **Computerized**	
Does the pharmacist review and check profiles prior to processing medication orders? **Yes** ☐ **No** ☐ • **If NO**, explain when profiles are checked: _____ _____	
Check what you record on profile: ☐ **Refills** ☐ **Prescriptions Only** ☐ **Both Refills and Prescription**	
Who performs the data entry (Rx, profile)? ☐ **R.Ph.** ☐ **Support Personnel**	
Are profiles retained and readily retrievable for 30 days after discharge? **Yes** ☐ **No** ☐	
Do profiles include the following information? a. Patient last and first name, address, phone number? **Yes** ☐ **No** ☐ b. Patient age or DOB? **Yes** ☐ **No** ☐ c. Prescriber's name and, for controlled substances, DEA # if available? **Yes** ☐ **No** ☐ d. Original date of the order, directions and stop date? **Yes** ☐ **No** ☐ e. Allergy information and chronic diseases? **Yes** ☐ **No** ☐ f. Initials of dispensing pharmacist? **Yes** ☐ **No** ☐	

24. **COMPUTER SYSTEMS Section 5.1.12 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Who is authorized to enter data into the computer system? _____	
What is the method of entry for each authorized person (e.g., individual access code, general access code)? _____	
Would another pharmacist or support person be able to enter prescription? **Yes** ☐ **No** ☐	
If there is a general access code, can the person who entered the data be identified? **Yes** ☐ **No** ☐	
Is computer used for other functions? **Yes** ☐ **No** ☐	
Does data entry of patient profiles comply with regulation? **Yes** ☐ **No** ☐	
Does data entry of prescription information comply with regulation? **Yes** ☐ **No** ☐	
Does data entered identify the responsible pharmacist(s) for each step in the dispensing process? **Yes** ☐ **No** ☐	
Does data entered remain online for at least one year from last entry? **Yes** ☐ **No** ☐	
Is data entered from one through three years ago available within five days? **Yes** ☐ **No** ☐	
If pharmacy records of the distribution, receipt, and dispensing of controlled substances are maintained centrally, is a copy of the letter notifying the DEA available? **Yes** ☐ **No** ☐	

25. **BACKUP RECORD KEEPING Section 5.1.12.5 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is there a back-up record-keeping system available if your computer is inoperative? **Yes** ☐ **No** ☐	
Does this back-up record-keeping system ensure that all renewals are authorized? **Yes** ☐ **No** ☐	
Does this back-up record-keeping system give you the ability to enter prescriptions dispensed and renewed while the computer is inoperative? **Yes** ☐ **No** ☐	

26. **DRUG DISTRIBUTION SYSTEM**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Describe drug distribution within the facility: _____ _____ _____ _____ _____	

27. **LABELING** [24 *Del C.* §2522]

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Do prescription labels show the following? • Patient name? **Yes** ☐ **No** ☐ • Specific directions (no "as directed" prescriptions)? **Yes** ☐ **No** ☐ • Drug name and strength? **Yes** ☐ **No** ☐ • Prescriber name? **Yes** ☐ **No** ☐ • Date/time of preparation? **Yes** ☐ **No** ☐ • Auxiliary labels for proper storage? **Yes** ☐ **No** ☐ • Expiration date/time of the medication? **Yes** ☐ **No** ☐	

28. **DISPENSING PHARMACY Section 5.0 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are automatic counting devices used in the pharmacy? • **If NO, skip to the next question.** **Yes** ☐ **No** ☐ • **If YES, does each cell contain the following:** a. Name of the drug? **Yes** ☐ **No** ☐ b. Manufacturer's name and NDC? **Yes** ☐ **No** ☐ c. Date filled? **Yes** ☐ **No** ☐ d. Batch/lot number and expiration date of the batch/lot? **Yes** ☐ **No** ☐	
Are all prescriptions maintained for a period of three years? **Yes** ☐ **No** ☐	
When a generic drug is dispensed, is the manufacturer or distributor noted on the original prescription and the label? **Yes** ☐ **No** ☐	
Are the initials of the filling/refilling pharmacist noted on the prescription and/or computer record? **Yes** ☐ **No** ☐	

29. **INVESTIGATIONAL DRUGS Section 9.2.1.11 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are any investigational drugs present/used at the facility? **Yes** ☐ **No** ☐ • **IF NO, skip to the CONTROLLED SUBSTANCES section**. • **IF YES, are the following requirements met**? a. Is control of dispensing maintained by pharmacy? **Yes** ☐ **No** ☐ b. Are only authorized physicians (investigators) allowed to prescribe investigational drugs and drug protocols are present? **Yes** ☐ **No** ☐ c. Is documentation available for the above? **Yes** ☐ **No** ☐ d. Does the label reflect that the medication is "investigational"? **Yes** ☐ **No** ☐ e. Does the label show the batch/lot number and expiration date? **Yes** ☐ **No** ☐	

30. **CONTROLLED SUBSTANCES 21 CFR 1300-1306 and Section 9.0 of the Pharmacy Rules and Regulations**

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are U.S. Official Order Form-Schedule II (DEA Form 222) (21 CFR 1305) and un-negotiated forms secure?	**Yes** ☐ **No** ☐	
Are the DEA Form 222s properly executed and retained for at least two years (21 CFR 1305.12)?	**Yes** ☐ **No** ☐	
Regarding invoices of controlled substances (21 CFR 1304.04 f 1, 2):		
• Are Schedule II order forms and invoices filed separately?	**Yes** ☐ **No** ☐	
• Are Schedule III – V invoices signed and dated upon receipt and filed separately from other invoices?	**Yes** ☐ **No** ☐	
• Are all invoices retained for at least two years?	**Yes** ☐ **No** ☐	
Regarding controlled substances that are returned for disposal (21 CFR 1307.21):		
• Are the drugs returned for disposal via the reverse distributor?	**Yes** ☐ **No** ☐	
• Are DEA Form 41 filed properly and retained for two years?	**Yes** ☐ **No** ☐	
Has there been any loss of controlled substances since the last review?	**Yes** ☐ **No** ☐	
• **If YES**, did you complete and submit a report of theft/loss of controlled substances to the Board and DEA (21 CFR 1301.76(b))?	**Yes** ☐ **No** ☐	
Was a biennial inventory of controlled substances completed (21 CFR 1304.11c)? • **If YES, date completed:** _____	**Yes** ☐ **No** ☐	
Did the Pharmacist-in-Charge (PIC) change after the last self-inspection? • **If YES,** answer these questions:	**Yes** ☐ **No** ☐	
a. PIC Start Date: _____	**Yes** ☐ **No** ☐	
b. Was the Pharmacy Board notified about the PIC change within ten days and was a copy of the notification retained onsite?	**Yes** ☐ **No** ☐	
c. Did the departing and incoming PICs do a complete inventory of controlled substances, submit it to the Office of Controlled Substances and retain a copy onsite? **IF YES, date compleed:** _____	**Yes** ☐ **No** ☐	
Are there policies and procedures for the following:		
• Wastage of controlled medications throughout the hospital (Section 9.2.1.7)?	**Yes** ☐ **No** ☐	
• Return of controlled substances to the pharmacy from various medication areas (Sections 9.2.1.8, 9.4.5)?	**Yes** ☐ **No** ☐	
• Discharge prescriptions?	**Yes** ☐ **No** ☐	
Does pharmacy routinely monitor/audit the use of controlled substances throughout the hospital?	**Yes** ☐ **No** ☐	
Are Schedule II prescriptions:		
• Filled separately from other prescriptions?	**Yes** ☐ **No** ☐	
• Properly cancelled and signed by the filling pharmacist ?	**Yes** ☐ **No** ☐	
• Not partially filled unless noted on the prescription that the patient is in a long-term care facility (“LTCF”) or is “terminally ill” and not exceeding 60 days from issue?	**Yes** ☐ **No** ☐	
• Listed in a perpetual inventory to audit on-hand quantities for accuracy? (Not a requirement)?	**Yes** ☐ **No** ☐ **N/A** ☐	
Is this pharmacy distributing controlled substances to other registrants including pharmacies, other hospitals, clinics and practitioners? • **If YES, answer these questions:**	**Yes** ☐ **No** ☐	
a. Are the Schedule II controlled substances distributed via DEA Form 222?	**Yes** ☐ **No** ☐	
b. Are the Schedule III-V controlled substances distributed via invoice?	**Yes** ☐ **No** ☐	

31. **CONTROLLED SUBSTANCES AUDIT**

Complete an audit of THREE controlled substances in at least TWO patient care areas (e.g., nursing unit, emergency room, operating room, etc.) using documentation of dispensing and administration since the last drug inventory.

At least one drug selected for audit must be Schedule II. The remaining two drugs may be Schedule II-V.

Complete the following table and calculate the percentage discrepancy as shown. ***Submit a report to the Board within 30 days to explain a discrepancy greater than:***

- ***0.2% for Schedule II medications, or***
- ***3% for Schedule III-V medications***

DATE OF LAST INVENTORY: _____				**DATE OF DRUG AUDIT: _____**			
AUDIT THREE DRUGS THAT WERE DISPENSED DURING THE AUDIT PERIOD. CHOOSING DRUGS THAT WERE NOT DISPENSED AND REPORTING "ZERO" SALES IS NOT ACCEPTABLE.							
NAMES OF DRUGS AUDITED	**LAST INVENTORY**	**PURCHASES SINCE INVENTORY**	**SALES SINCE INVENTORY**	**CALCULATED AMOUNT (=Last Inventory PLUS (+) Purchases , then subtract (-) Sales)**	**CURRENT INVENTORY**	**DISCREPANCY (subtract Current Inventory (-) from Calculated Amount)**	**% DISCREPANCY (divide Discrepancy by sum of Last Inventory and Purchases, then multiply by 100)**
Sample	*300*	***700***	***600***	***400***	***350***	***50***	***5%***

IF YOU HAVE CONCERNS ABOUT THE AUDIT, CONTACT THE OFFICE OF CONTROLLED SUBSTANCES FOR CLARIFICATION.

CERTIFICATION

Delaware law holds the pharmacist-in-charge responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to do so may result in fines and/or actions against the pharmacy and/or pharmacist license.

I, _____, Delaware Pharmacist license # A1 - _____, hereby certify that I have completed the self-inspection of this pharmacy of which I am pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy and/or the Office of Controlled Substances. I further state under penalty of perjury that the information contained in this self-inspection form is true and correct to the best of my knowledge and belief.

Signature of Pharmacist-in-Charge: _____ Date: _____